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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,899	03/31/2004	John Riley Hawkins	3518.1001-001	1803
21005	7590	12/09/2005	EXAMINER	
HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133			AMARELD JR, ROBERT W	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 12/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/813,899	Applicant(s) HAWKINS ET AL.	
	Examiner Robert W. Amareld, Jr.	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-53 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-13, drawn to a method of implanting a disc, classified in class 606, subclass 86.
- II. Claims 14-53, drawn to the apparatus, classified in class 606, subclass 86.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the kit of invention II could be used to place a replacement core implant into a bone from which a core sample has been drilled or cut from.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

Upon election of the apparatus, further restriction to one of the following inventions is required under 35 U.S.C. 121:

- i. Claims 14-24, drawn to a kit for implanting an intervertebral disc, classified in class 606, subclass 86.
- ii. Claim 25-28, drawn to verification instrument, classified in class 606, subclass 61.
- iii. Claims 29—30, 52-53, drawn to a midline marker, classified in class 606, subclass 61.
- iv. Claims 31-35, drawn to an endplate cutting device, classified in class 606, subclass 79.
- v. Claims 36-37, drawn to a distraction instrument, classified in class 606, subclass 105.
- vi. Claims 38-40, drawn to an endplate insertion instrument, classified in class 606, subclass 99.
- vii. Claim 41-43, drawn to a core insertion instrument, classified in class 606, subclass 99.
- viii. Claims 44-51, drawn to a trial spacer head, classified in class 606, subclass 102.

The inventions are distinct, each from the other because of the following reasons:

Inventions i and ii are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP §

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806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the subcombination contains a pin with an extending horizontal portion and extending vertical portion (claim 26) and a guide consisting of a slot or bore (claim 28), not necessary for the combination. The subcombination has separate utility such as a slotted guided for a bone-cutting device.

Inventions i and iii are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the subcombination contains the particulars of at least one or two protrusions (claim 29) and retention spikes (claim 30), not necessary for the combination. The subcombination has separate utility such as a bone plate retained to the bone by the retention spikes.

Inventions i and iv are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the subcombination contains the

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particulars of a handle (claim 31) or discrete graduations (claim 34) or cutting shafts (claim 31), not necessary for the combination. The subcombination has separate utility such as cutting and shaping device for bone segments such as the femur or humerus or distracting and cutting apart bones such as the femur and the tibia.

Inventions i and v are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the subcombination contains the particulars of removably coupled diametrically opposed arms and a distraction mechanism (claims 36 & 37), not required by the combination. The subcombination has separate utility such as being used in the reverse action of distraction as tongs to pick up an object or push two object together.

Inventions i and vi are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the subcombination contains the

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particulars of an endplate holder, a handle, a slidably coupled mounting plate (claim 38) or a removably coupled insertion end (claim 42), not required by the combination. The subcombination has separate utility such as a guide for an orthopedic plate to be attached to other bones of the body such as the humerus or femur.

Inventions i and vii are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the subcombination contains the particulars of a removably coupled insertion end, not required by the combination. The subcombination has separate utility such as a guide for a guide for returning a core sample back to its source, such as returning a tree core sample to its parent tree ensure adequate healing of the tree.

Inventions ii and viii are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the subcombination contains the

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particulars of a radiopaque body (claim 45) or diametrically opposed pins of different lengths (claim 46 & 48), not required by the combination. The subcombination has separate utility such as a temporary bone implant that could be placeholder until a permanent implant is available.

Inventions ii, iii, iv, v, vi, vii & viii are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant each case invention has separate utility such as indicated below. See MPEP § 806.05(d).

ii. Verification instrument

- a. Separate utility as a slotted guided for a bone-cutting device.

iii. Midline marker

- a. Separate utility as a bone plate retained to the bone by the retention spikes.

iv. Endplate cutting device

- a. Separate utility as a cutting and shaping device for bone segments such as the femur or humerus or distracting and cutting apart bones such as the femur and the tibia.

v. Distraction instrument

- a. Separate utility, such as being used in the reverse action of distraction as tongs to pick up an object or push two object together.

vi. Endplate insertion instrument

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- a. Separate utility as a guide for an orthopedic plate to be attached to other bones of the body such as the humerus or femur.
- vii. Core insertion instrument
 - a. Separate utility as a guide for a guide for returning a core sample back to its source, such as returning a tree core sample to its parent tree ensure adequate healing of the tree.
- viii. Trial spacer head
 - a. Separate utility as a temporary bone implant that could be placeholder until a permanent implant is available.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Upon election of **Group ii** further election of species is required

A. Figure 1b, 18

B. Figure

Upon election of **Group iii** further election of species is required

A. Figure 3A

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B. Figure 12A

C. Figure 12D

Upon election of **Group iv** further election of species is required

A. Figure 4A

B. Figure 13A

Upon election of **Group v** further election of species is required

A. Figure 2A

B. Figure 8A

C. Figure 8D

D. Figure 8E

Upon election of **Group vi** further election of species is required

A. Figure 5A

B. Figure 14A

C. Figure 14E

Upon election of **Group vii** further election of species is required

A. Figure 6A

B. Figure 15A

C. Figure 15E

Upon election of **Group viii** further election of species is required

A. Figure 2B

B. Figure 10A

C. Figure 10E

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, none are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert W. Amareld, Jr. whose telephone number is 571-272-6170. The examiner can normally be reached on M-F 9am -5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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